Texas Department of State Health Services, Health Service Regions, Standing Delegation Orders for Tuberculosis Clinical Services Provided by Authorized Licensed Nurses and Paramedics, Fiscal Year 2017-18

The purpose of this document is to provide authority for specific acts of tuberculosis (TB) clinical services under authority of Texas Administrative Code, Title 22, Part 9, Chapter 193 (§193.2), Standing Delegation Orders.

Standing delegation orders (SDOs) and standing medical orders (SMOs) are written instructions, orders, rules, regulations or procedures prepared by a physician. SDOs provide authority and a plan for use with patients presenting themselves prior to being examined or evaluated by a physician. SMOs provide authority and direction for the performance of certain prescribed acts for patients which have been examined or evaluated by a physician. SDOs and SMOs are distinct from specific orders written for a particular patient. The Texas TB Work Plan and the 2016 Official ATS/CDC/IDSA Clinical Practice Guidelines for the Diagnosis of Tuberculosis in Adults and Children and the Treatment of Drug-Susceptible Tuberculosis should be used as companions to this SDO in order to ensure all patient care standards are met.

The intended audience for these orders is authorized licensed registered and vocational nurses and licensed paramedics working in Texas Department of State Health Services (DSHS) Health Service Regions (HSRs).

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Standing Delegation Orders

A. Definitions

1. Authorized Licensed Nurse or paramedic: an employee or contractor of DSHS in a nursing position who is licensed to practice by the Texas Board of Nursing who has met the requirements of and signed this SDO.

2. Authorized Licensed Paramedic: A paramedic who is an employee or contractor of DSHS, has a current, unexpired license in Texas, and has met the requirements of and signed this SDO.

2. Treating Physician: a physician licensed by the Texas Medical Board who executes this SDO.
3. Acronyms and Explanations:

IGRA	Interferon Gamma Release Assay, a blood test for TB infection. There are two types: T-Spot and QFT (QuantiFERON Gold)
TST	TB skin test; sometimes referred to as PPD (purified protein derivative) which is the material injected intradermally. Area is examined 24-72 hours later for induration/elevation of skin to measure the patient's immune system response to TB antigens.
CXR	Chest x-ray
PA CXR	Posterior-anterior CXR; one view of the chest taken with the patient's back to the x-ray machine.
Lateral CXR	CXR is taken with the patient lined up side-ways.
AFB	Acid-fast bacilli is a technical term for TB bacteria because, in laboratory testing, they retain a stain even after washing with acid and they are rod-shaped bacteria (i.e. bacillus)
CBC	Complete blood count
CMP	Complete metabolic panel; monitor liver and kidney function
LTBI	Latent TB infection; medical condition of being infected with TB (+TST or IGRA) but not sick/no symptoms and not contagious
DOT	Directly observed therapy
DOPT	Directly observed preventive therapy
MDR-TB	Multi-drug resistant TB; resistant to INH and RIF
3HP	Treatment regimen for LTBI; INH and Rifapentine (RPT) are given once weekly for 12 weeks
ART	Anti-retroviral therapy for HIV

B. Method Used for Development, Approval, and Revision

This SDO and the relevant attachments shall be:

1. Developed by the DSHS Regional Medical Directors in consultation with DSHS TB nurses and in accordance with the Official American Thoracic Society/Infectious Diseases Society of America/Centers for Disease Control and Prevention Clinical Practice Guidelines for the Diagnosis of Tuberculosis in Adults and Children and the Treatment of Drug-Susceptible Tuberculosis.

2. Reviewed and signed at least annually by the treating physician.

3. Revised as necessary by the Regional Medical Directors in consultation with DSHS TB nurses, the DSHS TB Program, and/or Infectious Disease Medical Officer.

4. Reviewed as needed by TB expert physician(s) at the Heartland National Tuberculosis Center.

C. Level of Experience, Training, Competence, and Education Required

To carry out acts under this SDO, an authorized licensed nurse or paramedic must:

1. Be an employee or contractor of DSHS.

2. Be currently licensed to practice by the Texas Board of Nursing or as a Paramedic by The Department of State Health Services.

3. Be currently certified in Basic Life Support.

4. Been fit tested for N95 respirator.

5. Been screened for TB within the past 12 months according to one of the following:

    a History of LTBI treatment: documentation is in employee's file AND no signs or symptoms of TB on questionnaire.
    b History of prior positive TB test (TST or IGRA): documentation is in employee's file AND no signs or symptoms of TB on questionnaire. Consult with authorizing physician for further evaluation and management as necessary.
    c Tested positive for TB during annual screening: no signs or symptoms of TB on questionnaire AND normal CXR (or not consistent with TB) AND offered treatment in consultation with the authorizing physician.
    d Tested negative on TB test.

6. After hire, within the timeframe for new employees, have successfully completed the following training and/or reviewed the following documents before providing services under this SDO:
    a Core Curriculum on Tuberculosis: What the Clinician Should Know, 6th Edition. CDC, 2013. http://www.cdc.gov/tb/education/corecurr/pdf/corecurr_all.pdf
    b Bloodborne Pathogen Prevention training and post-test evaluation. http://online.dshs.state.tx.us/idcu/Bloodborne-Safety.aspx
    c CDC Fact Sheet "Tuberculin Skin Testing"

http://www.cdc.gov/tb/publications/factsheets/testing/skintesting.htm

d CDC fact sheet "Targeted Tuberculin Testing and Interpreting Tuberculin skin Test Results" http://www.cdc.gov/tb/publications/factsheets/testing/skintestresults.htm

e Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis. MMWR 2005; 54(RR15): 1-55. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5415a1.htm

7. Annually, have completed the following training as continuing education and occupational health requirements:
   a Bloodborne Pathogen Prevention training and post-test evaluation. http://online.dshs.state.tx.us/idcu/Bloodborne-Safety.aspx
   b Fit testing for N95 respirator.
   c TB Screening (details above).
   d Review of:
      1 Official American Thoracic Society/Infectious Diseases Society of America/Centers for Disease Control and Prevention Clinical Practice Guidelines: Diagnosis of Tuberculosis in Adults and Children. CID, 2016; 00(0): 1-33. https://www.thoracic.org/statements/resources/tb-opi/diagnosis-of-tuberculosis-in-adults-and-children.PDF
      2 Official American Thoracic Society/Infectious Diseases Society of America/Centers for Disease Control and Prevention Clinical Practice Guidelines: Treatment of Tuberculosis in Adults and Children. CID, 2016; 63(7): e147-95. https://www.cdc.gov/tb/publications/guidelines/pdf/clin-infect-dis.-2016-nahid-cid_ciw376.pdf

8. Completion of the initial (within the timeframe for new employees) or annual evaluation of TB knowledge and competence in TB clinical services before signing and providing services under this SDO:
   a If the nurse's supervisor is not a licensed clinician, one will be designated by the Communicable Disease Manager who shall be responsible for the evaluation.
   b The initial or annual evaluation must consist of verification that the authorized licensed nurse or paramedic possesses a valid nursing license or paramedic certification, post-test evaluation of initial or annual education and knowledge, verification of TB screening and fit testing, and observation of the required clinical skills.
   c For authorized licensed nurses or paramedics whose primary job duties are with the TB program, this training and evaluation of competence must occur within 90 days of employment. For other

authorized licensed nurses or paramedics who provide TB services, this training and evaluation of competence must occur before TB clinical services are independently provided by the nurse or paramedic.

9. Are familiar with the following documents which must be readily available to the authorized licensed nurse or paramedic to consult as needed:
    a Official American Thoracic Society/Infectious Diseases Society of America/Centers for Disease Control and Prevention Clinical Practice Guidelines: Diagnosis of Tuberculosis in Adults and Children. CID, 2016; 00(0): 1-33. https://www.thoracic.org/statements/resources/tb-opi/diagnosis-of-tuberculosis-in-adults-and-children.PDF
    b Official American Thoracic Society/Infectious Diseases Society of America/Centers for Disease Control and Prevention Clinical Practice Guidelines: Treatment of Tuberculosis in Adults and Children. CID, 2016; 63(7): e147-95. https://www.cdc.gov/tb/publications/guidelines/pdf/clin-infect-dis.-2016-nahid-cid_ciw376.pdf
    c Screening for Tuberculosis and Tuberculosis Infection in High-Risk Populations Recommendations of the Advisory Council for the Elimination of Tuberculosis. MMWR. 1995; 44(RR11):18-34. http://www.cdc.gov/MMWR/preview/MMWRhtml/00038873.htm
    d Recommendations for Human Immunodeficiency Virus (HIV) Screening in Tuberculosis (TB) Clinics Fact Sheet. http://www.cdc.gov/tb/publications/factsheets/testing/HIVscreening.htm
10. Are aware of and able to readily access the following documents:
    a Recommendations for Use of an Isoniazid–Rifapentine Regimen with Direct Observation to Treat Latent *Mycobacterium tuberculosis* Infection. MMWR. 2011; 60(48):1650–1653. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6048a3.htm?s_cid=mm6048a3_w
    b Latent Tuberculosis Infection: A Guide for Primary Health Care Providers. Centers for Disease Control and Prevention. 2013. https://www.cdc.gov/tb/publications/ltbi/pdf/TargetedLTBI.pdf
    c Updated Guidelines for the Use of Nucleic Acid Amplification Tests in the Diagnosis of Tuberculosis. MMWR. 2009; 58(1):7-10.http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5801a3.htm?s_cid=mm5801a3_e
    d An Official ATS Statement: Hepatotoxicity of Antituberculosis Therapy. Am J Respir Crit Care Med. 2006; 174:935-952. http://www.thoracic.org/statements/resources/mtpi/hepatotoxicity-of-antituberculosis-therapy.pdf
    e Controlling Tuberculosis in the United States Recommendations from

the American Thoracic Society, CDC, and the Infectious Diseases Society of America. MMWR. 2005; 54(RR12):1-81. http://www.cdc.gov/MMWR/preview/MMWRhtml/rr5412a1.htm

f Recommendations for Prevention and Control of Tuberculosis among Foreign-Born Persons. MMWR. 1998; 47(RR16):1-26. http://www.cdc.gov/MMWR/preview/MMWRhtml/00054855.htm

g Prevention and Control of Tuberculosis in Migrant Farm Workers Recommendations of the Advisory Council for the Elimination of Tuberculosis. MMWR. 1992; 41(RR10). http://www.cdc.gov/MMWR/preview/MMWRhtml/00032773.htm

h Prevention and Control of Tuberculosis among Homeless Persons Recommendations of the Advisory Council for the Elimination of Tuberculosis. MMWR. 1992; 41(RR5):001. http://www.cdc.gov/MMWR/preview/MMWRhtml/00019922.htm

i Prevention and Control of Tuberculosis in Facilities Providing Long-Term Care to the Elderly Recommendations of the Advisory Council for the Elimination of Tuberculosis. MMWR. 1990; 39(RR10):7-20. http://www.cdc.gov/MMWR/preview/MMWRhtml/00001711.htm

11. Have reviewed and agreed to follow the orders in this SDO by signing the *Attestation of Authorized Licensed Nurse or Paramedic (*Attachment 1) within the 12 months prior to providing services under this SDO.

D. Method of Maintaining a Written Record of Authorized Licensed Nurses or Paramedics

The record that an authorized licensed nurse or paramedic has completed the required training and demonstrated competence to operate under these SDOs shall be maintained by the nurse's or paramedic's supervisor in the Region 8 headquarters. These SDOs with the treating physician's signature and the *Attestation of Authorized Nurse or Paramedic (*Attachment 1*)* will be uploaded to the RLHS Sharepoint site, SDO Folder.

E. Authorized Delegated Acts

Authorized licensed nurses or paramedics may evaluate and provide TB clinical services under this SDO to patients who are undergoing evaluation for suspected TB disease or TB infection or are being treated for TB disease or infection.

Such clinical services may include:

a. Obtain, review, and record medical history of patients and obtain medical records.
b. Perform appropriate medical screening procedures.
c. Obtain specimens for laboratory testing.

d. Link patients to services for social needs or for medical evaluation and management for comorbidities.
e. Provide treatment to patients prescribed by the treating physician.
f. Interview and perform medical screening procedures for patients to determine the presence of signs and symptoms of TB disease, response to treatment, and medication toxicity.
g. Coordinate with other regional nurses involved in the patient's care, licensed medical providers, state and/or local health departments, detention facilities, hospital infection control practitioners, Heartland National TB Center, and the DSHS TB Program as needed.
h. Perform monthly toxicity evaluations involving physical assessments and blood draws.
i. Evaluate laboratory results for follow-up.
j. Identify abnormal findings and refer to the physician for direction.
k. Notify the treating physician of critical lab values, patients with signs or symptoms of medication toxicity, and patients with worsening signs or symptoms of TB.
l. Notify the treating physician and Regional Medical Director if there has been TB exposure in a congregate setting. Notification should be immediate if the setting is a school, a hospital, a day-care, any facility caring for children under 5 years of age, or any facility caring for adults with multiple medical problems such as dialysis centers, nursing homes, or adult day-cares.

It is the intent of all parties that the acts performed under this SDO shall be in compliance with the Texas Medical Practice Act, the Texas Nursing Practice Act, the Texas Pharmacy Act, and the rules promulgated under those Acts.

F. Procedures and Requirements to be followed by Authorized Licensed Nurses or paramedics

1. Adhere to all Standard Precautions when participating in TB clinical services.

2. At initial contact, determine the patient's preferred language and utilize interpreter services to facilitate patient and provider communication. *Always confirm with the patient and document that he/she understands the information provided.*

3. Ensure, to the extent possible, that the patient seen for TB clinical services is, in fact, who the person claims to be.

4. Establish that the patient requires evaluation for TB disease or TB infection or is a contact to a confirmed or suspected TB disease case.

5. Always explain tuberculosis infection and disease, tests to be performed, and any treatment to the patient and give time for questions.
    a. Obtain the patient's signature or, if the patient is a child or has a disability that prevents informed consent, the parent's or caregiver's signature on the DSHS General Consent form and privacy acknowledgement before performing any testing or providing any treatment.
    b. Provide copies of the HIPAA privacy notice and signed consent form to the patient and place the originals in the medical record.
        DSHS General Consent and Disclosure (L-36), available at: www.dshs.state.tx.us/rls/pubs/GeneralConsentForm042010.pdf
        DSHS Privacy Notice, available at: http://www.dshs.state.tx.us/hipaa/privacynotices.shtm
    c. For patients suspected or confirmed to have TB disease, provide the *Order to Implement and Carry out Measures for a Patient with TB*, TB-410, TB-410A (Spanish) or TB-410B for children, ("Control Order", "Health Authority Warning Letter"), signed and dated by the local health authority, for the patient to review.
        - Explain the Control Order and risks of violation of the Control Order in the patient's preferred language.
        - Provide the opportunity for the patient to ask questions.
        - Have the patient review and sign the Control Order.
        - Provide a copy of the Control Order to the patient.
        - If the patient has questions the authorized licensed nurse or paramedic cannot answer, contact the local health authority.

6. **Isolation:** Explain to the patient, in his/her preferred language, that he/she must remain in isolation until one of the following set of criteria are met:
    a. Patients with sputum that is AFB smear positive must meet all of the following to be released from isolation:
        - Have three consecutive negative sputum smears, collected between 8 and 24 hours apart AND
        - Have demonstrated symptomatic and/or radiographic improvement AND
        - Have been on treatment for TB for at least two weeks given as DOT.
    b. Patients whose first three sputum specimens are AFB smear negative must meet both of the following to be released from isolation:
        - Have symptomatic improvement AND
        - Have been on treatment for TB for at least 5 days given as DOT.

7. **Counsel** patients about potential medication side effects
    a. Explain possible medication side-effects, signs and symptoms of toxicity,

and conditions under which medications should be stopped.

b. If the patient is a woman of child-bearing age, counsel her on the need to use additional protection to prevent pregnancy, if appropriate.
c. Have patient review and sign the TB-411 or TB-411A or equivalent with the patient's medications circled/marked. Provide a copy to the patient.
d. Provide contact information for nurse(s) the patient should contact should he/she develop side effects.

8. **Create a medical record** and ensure it remains up to date including:
   a. All forms and progress notes
   b. Documentation of every patient encounter
   c. All test collection dates, test types, circumstances affecting collection, and results
   d. Lab test reports
   e. Documentation of review of all diagnostic test results
   f. DSHS TB forms can be found at: http://www.dshs.texas.gov/IDCU/disease/tb/forms/

9. Interview the patient to obtain a **medical history and health assessment** (TB-202 or equivalent). Obtain, at a minimum, the following information:
   a. At initial patient evaluation:
      - A history of the patient's current illness: signs and/or symptoms (s/s), their onset date, medical care received for current illness, and timeline and worsening of s/s.
      - TB Medical history: history of TB disease, previous treatment for TB, family members with a history of TB, any other known exposures, previous positive TB screening test.
      - Social and Medical Risk factors for TB (TB-400A)
      - Medical and surgical history
      - Current medications including vitamins/supplements, over-the-counter medications, and traditional medicines/remedies
      - Allergies
      - Social situation and need for services
   b. At monthly toxicity visits or as needed:
      - Signs and symptoms of TB and their improvement or worsening over time.
      - New signs and symptoms, including their start date and progression over time.
      - New medications.
      - Social situation and need for services.

17. Perform a **physical examination** which includes, at a minimum:
   a. At initial patient visit:

- Observe general condition, alertness, and orientation to person, place, and time.
- Measure blood pressure, heart rate, temperature, and **weight**
- Measure visual acuity using Snellen chart and assess color vision using the Ishihara plates, if the patient is taking **Ethambutol**
- Palpate lymph nodes. (see Attachment 11*)*
  - It is especially important in children to carefully palpate for enlarged lymph nodes in all the locations in the attachment and document the findings
  - For adults, at a minimum palpate axillary and cervical nodes.
  - If patient has **lymph node TB**:
    1. Measure and document the size and appearance (redness, drainage)
    2. Take picture without including patient's face or other identifying features
- If patient has **extra-pulmonary TB** and location is visible externally, examine and document appearance
  1. Measure size if applicable
  2. Take picture without including patient's face or other identifying features.

b. At monthly toxicity visits or as needed:

- Observe general condition, alertness, and orientation to person, place, and time
- Measure blood pressure, heart rate, and temperature
- Measure **weight.** Notify treating physician if patient is losing weight and enquire about diet and access to food
- Measure visual acuity using Snellen chart and assess color vision using the Ishihara plates, if the patient is taking **Ethambutol**
- Examine exposed skin for rashes, including rolling up sleeves and/or pants if necessary. Take picture of any rashes without any identifying features.
- If patient has **lymph node TB**:
  1. Measure and document any changes in size and appearance
  2. Take picture without including patient's face or other identifying features.
- If patient has **extra-pulmonary TB** and location is visible externally, examine and:
  1. Document changes in size or appearance if applicable
  2. Take picture without including patient's face or other identifying features.

18. **Chest X-Rays (CXRs)**

a. Views to be ordered, at a minimum (or as ordered by the treating physician)
    - Patients 18 years of age and younger: PA and lateral CXR
    - Adults over 18 years of age: PA CXR
b. Frequency, at a minimum:
    - At initiation of treatment for a baseline.
    - After the initiation phase (first 2 months of treatment) to assess response.
    - At completion of treatment.
c. Refer for a CXR if a patient reports worsening of TB symptoms.
d. When submitting CXRs to radiology, include the initial CXR and any others during treatment for comparison.

19. **TB Screening tests**
    a. TSTs are recommended for children from 6 months to 5 years of age *(*procedures in Attachments 9 and 10)
    b. IGRAs are recommended for anyone 5 years of age or older (venipuncture procedure in Attachment 17)
        - If a QFT is reported as *indeterminate* or a T-Spot is reported as *borderline*, repeat the test.
        - If the test comes back indeterminate or borderline a second time, notify the treating physician for orders.
    c. Do not perform any TB screening test if the patient has:
        - Documentation of a prior positive
        - A history of treatment for TB
        - Documented active TB
    d. Do not perform an IGRA test if:
        - The patient has received a live virus vaccine within the last 4 to 6 weeks. They can be given at the same time, however.
        - A TST has been placed within the past 3 months.
    e. Do not perform a TST:
        - If an infant is less than 6 months of age.
        - Allergy to any component of TUBERSOL or APLISOL or an anaphylactic or other allergic reaction/hypersensitivity to a previous test of tuberculin purified protein derivative (PPD)
        - Severe reaction to previous TST such as ulceration, necrosis, blistering, bullae, anaphylaxis
        - A documented history of treatment for TB infection or disease
        - Extensive burns or eczema

20. **Patients under 5 years of age, HIV positive, or immunocompromised being evaluated for TB infection or disease**:
    a. Place TST or IGRA appropriate for age.
    b. Refer for PA and lateral CXR, preferably at the same time but regardless

of the result of the TB screening test.

c. Obtain history of signs and/or symptoms of TB.
d. Perform physical examination.

21. **Sputum Collection** *(*Attachment 14)
    a. Collect sputum at initial visit for patients being evaluated for TB disease or as ordered by the treating physician and send for NAAT (first one), smear, and culture.
    b. Three sputum specimens should be collected every two weeks until three consecutive AFB smears are negative.
    c. If the first three sputum specimens are AFB smear negative, collect one specimen per month as above until two consecutive cultures are negative one month apart.
    d. Once the patient's sputum smears have converted to negative, collect one sputum monthly until two consecutive cultures are negative for TB one month apart.
    e. Sputum specimens must:
        - Be collected between 8 and 24 hours apart.
        - One sputum specimen should be collected first thing after the patient wakes up in the morning.
    f. If the patient is having trouble producing sputum, use the nebulizer to induce sputum production according to the procedure in *Attachment 15*
    g. Collect three sputum specimens if a patient has confirmed extrapulmonary TB to rule out pulmonary involvement.
    h. Handle, package, and ship specimens according to procedure in *Attachment 16*

22. **Laboratory Tests** (Attachment 17: Venipuncture Procedure)
    a. Complete Blood Count (CBC) and Complete Metabolic Panel (CMP)
        - Draw blood for these lab tests at first visit unless the patient was tested with normal results within the past 14 days.
        - Draw blood for CMP and CBC every month at toxicity assessment.
        - If at any time, CBC or CMP are abnormal, provide the reports to the treating physician for review.
        - If any values are reported as critical, notify the treating physician immediately.
        - Consider diabetes if the blood glucose level on the CMP is:
            1. ≥200 mg/dL and patient was not fasting
            2. ≥126 mg/dL and the patient reports not eating or ingesting any calories for 8 hours or more
            3. If diabetes is suspected or known and uncontrolled, link the patient to a healthcare provider for further evaluation and

management. Consult a regional social worker if assistance is needed.

b. **HIV** (for patients 13 years of age or older)
   - Draw blood for HIV testing unless the patient is a prior positive or has documentation of a negative test in the past 14 days.
   - If the patient has a history of HIV:
     1. Notify treating physician and regional HIV/STD program.
     2. Obtain CD4 count, viral load, and anti-retroviral treatment regimen.
     3. If the patient is not receiving HIV services, work with regional HIV/STD program to link to HIV care.
   - If the patient has a new diagnosis of HIV:
     1. Refer the patient to the regional HIV/STD team and for linkage to HIV care.
     2. Notify treating physician.
     3. Closely coordinate and share information with the HIV clinic where the patient obtains services.
     4. Coordinate lab testing with the patient's HIV clinic to minimize blood draws.

c. Evaluate patient for risk factors for **Hepatitis B** and screen if indicated according to the following criteria:
   - Screen patient for HBV if any of the following risk factors apply. Draw blood to test for Hepatitis B surface Antigen (HBsAg):
     1. For foreign-born patients from high risk regions (highest risk is in the first two regions.
        a. Western Pacific (includes China, Cambodia, Vietnam, the Philippines, Korea)
        b. Africa (Congo, Ethiopia, Guinea, Kenya, Eritrea, Sierra Leone)
        c. Southeast Asia (Bangladesh, Nepal, India, Myanmar/Burma)
        d. Eastern Mediterranean (Afghanistan, Iraq, Kuwait, Pakistan, Yemen, Sudan, Syria)
     2. US-born patients born to parents from a high risk regions who were not vaccinated
     3. Household members of HBsAg positive persons
     4. Men who have sex with men
     5. IV drug users (current or in the past)
     6. Patients with liver disease or elevated liver enzymes without known cause
     7. HIV+ patients

8. Pregnant patients (obtain results for healthcare provider). If the patient is not in pre-natal care, link to care. Consult regional Specialized Health and Social Services program (SHSS) if necessary.
9. Persons receiving cytotoxic or immunosuppressive therapy (consult treating physician)

- Screening is not necessary for:
  - Patients with a previously documented positive HBV test result.
  - Patients with a documented negative HBV test result within the last 14 days.
  - Obtain a copy of the results and document in the patient's medical record.
- For patients with a new diagnosis of HBV refer for further evaluation and management. Consult a regional social worker if assistance is needed.

d. Evaluate patient for risk factors for **Hepatitis C** and screen if indicated according to the following criteria:
   - Screen patients by drawing blood for HCV antibody if any of the following risk factors apply:
     - IV drug user (currently or in the past)
     - History of incarceration
     - History of an unregulated tattoo
     - Have ever used drugs intranasally
     - Have certain medical conditions, including persons:
       - Who received clotting factor concentrates produced before 1987
       - Who were ever on long-term hemodialysis
     - Have persistently abnormal ALT levels without known cause
     - Received a transfusion of blood, blood components or an organ transplant before July 1992
   - Screening is not necessary for the following, but obtain documentation for the patient's chart:
     - Patients with a documented positive HCV test result.
     - Patients with a documented negative HCV test result within the last 14 days

23. **Medication Administration**

a. Have emergency kit available and remain with the patient for 30 minutes after administration for at least the first two doses.
b. At follow-up visits following the first dose, screen patient for signs and symptoms of medication toxicity.
   1) If any are reported, DO NOT give medications.

2) Draw CMP and/or CBC
3) Notify treating physician

c. Review the medication regimen ordered by the treating physician and check that:
   1) The medications in the DOT packet match those prescribed by the treating physician.
   2) The doses are correct and calculated correctly if based on weight (Attachments 18, 19, 20*)*
   3) Vitamin B6 is prescribed if INH is being given for anyone over 13 years of age.
   4) There are no new medications and/or any drug interactions that haven't been addressed by the treating physician.
      i. Resources include the DSHS Pharmacist and the DSHS Library's access to "Facts and Comparisons,"
      ii. Heartland National TB Center has produced tables of interactions of rifamycins with diabetic, hypertensive, and psychotropic medications. These can be found at:
      - http://www.heartlandntbc.org/assets/products/Rifamycins%20and%20Anti-Diabetic%20Agents_2012.pdf
      - http://www.heartlandntbc.org/assets/products/rifamycins_and_cardiovascular_agents_drug_drug_interactions.pdf
      - http://www.heartlandntbc.org/assets/products/rifamycins_and_psychotropic_drugs.pdf

d. Administer medications while observing the patient ingest all of them. **DOT or DOPT** is required for:
   1) All patients with diagnosed or suspected TB disease
   2) All contacts on window prophylaxis
   3) Any children under 5 years of age on treatment for LTBI
   4) All patients receiving an intermittent regimen for LTBI (3HP or INH twice weekly)
   5) All patients being treated for LTBI who were a contact to a patient with MDR-TB

e. If instructed to leave medication packets with the patient for self-administration. (procedure is in Attachment 22)

24. **Patient monitoring**

a. Every patient must be assessed monthly by an authorized licensed nurse or paramedic for possible toxicity to the medications and for response to treatment.

b. The assessment must include, at a minimum:
   1) Interviewing the patient for:
      i. Signs and symptoms of medication toxicity
      ii. Changes in TB signs and symptoms
   2) Drawing blood for CMP and CBC

3) Measuring blood pressure, heart rate, temperature, and weight
4) If patient is on Ethambutol, measuring visual acuity and assessing color vision.
5) Checking skin for rashes.
6) Checking sclera and skin for yellow discoloration

c. Notify treating physician if any significant changes or abnormalities are identified.
d. If the patient is inconsistent in meeting for DOT or if there is an interruption in treatment over a week consult the treating physician.

24. **Packaging and Shipping:** Label and correctly package specimens, according to shipping requirements and regional procedures. Submit specimens to the appropriate lab with the properly completed lab form (Attachment 16).

25. For **verbal or telephone orders** or telephonic reporting of critical test results to the treating physician:
    a. Document the complete order and/or abnormal test result on a progress note
    b. Read it back to the treating physician for approval
    c. Document if the treating physician gives approval with date and time and notation that it was done verbally
    d. Place progress note in the medical record
    e. Obtain signature or electronic confirmation from the treating physician as soon as possible, ideally within one week, and include in medical record

26. Coordinate with the TB program, other regional programs, healthcare providers, local health departments, detention facilities, hospitals, TCID, and/or other states' public health agencies in the evaluation and treatment of patients with confirmed or suspected TB disease and contact investigations.

27. If the patient violates the **Control Order**, immediately notify the treating physician.

28. Determine **completion of therapy** based on total number of doses administered not on duration of therapy alone and report to the treating physician.

It is the intent of all parties that the acts performed under this SDO shall be in compliance with the Texas Medical Practice Act, the Texas Nursing Practice Act, the Texas Pharmacy Act, the Texas Occupations Code Title 3: Health Professions, and the rules promulgated under those Acts.

It is also the intent that these SDOs follow the Clinical Practice Guidelines: Treatment of Drug-Susceptible Tuberculosis published in 2016 that can be found at https://www.cdc.gov/tb/publications/guidelines/pdf/clin-infect-dis.-2016-nahid-cid_ciw376.pdf.

H. Scope of Supervision Required

This SDO gives the authorized licensed nurse or paramedic the authority to perform the acts faithfully as written with consultation of the treating physician as needed.

I. Specialized Circumstances to Immediately Contact the Treating Physician

1 Any of the patient's liver function tests (aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase (alk phos), and/or total bilirubin) exceed three times the upper limit of normal:
   a. Interview the patient and obtain information about:
      1) If the patient reports any signs or symptoms of hepatotoxicity, **DO NOT GIVE MEDICATIONS**: nausea, vomiting, abdominal pain (especially right upper quadrant), yellowing of the skin or the sclera of the eyes, loss of appetite, fatigue, itching, fainting or near fainting.
      2) Ask the patient about:
         - Any newly prescribed medications.
         - Any new over-the-counter medications (especially Tylenol), supplements, and/or herbal remedies including herbal teas.
         - Any alcohol or drug use.
   b. Re-educate patient to avoid anything hepatotoxic.
2 Any of the patient's liver function tests (LFTs) exceeds five times the upper limit of normal.
   a. Regardless of the presence of signs or symptoms of hepatotoxicity, **Do not give medications**
      1) Carefully assess the patient for complaints of nausea, vomiting, abdominal pain (especially right upper quadrant), yellowing of the skin or sclera of the eyes, loss of appetite, fatigue, itching, fainting or near fainting.
      2) Ask about any newly prescribed medications
      3) Ask about use of any new over-the-counter medications that contain acetaminophen (Tylenol), supplements, or herbal remedies including herbal teas
      4) Ask about alcohol or drug use.
      5) Re-educate patient to avoid anything that is hepatotoxic
   b. Re-ducate patient on signs and symptoms of hepatotoxicity and instruct him/her to call the nurse or paramedic overseeing clinical management of the patient and seek immediate medical assistance if these worsen.

c. Review case with treating physician.

3 Lab results reveal a significant change and/or increase, as defined by the treating physician.

4 Critical values are reported.

5 If the patient reports any of the following signs and/or symptoms **DO NOT GIVE MEDICATIONS,** assess the patient, obtain history of onset and progression, and **notify the treating physician immediately:**

a. Any signs or symptoms of hepatotoxicity: nausea, vomiting, abdominal pain (especially right upper quadrant), yellowing of the skin or sclera of the eyes, loss of appetite, fatigue, itching, fainting or near fainting.
   1) Draw blood for CMP
   2) Ask about any newly prescribed medications, new over-the-counter medications that contain acetaminophen (Tylenol), supplements, or herbal remedies including herbal teas
   3) Ask about alcohol or drug use.

b. Blisters or sores in the mouth.

c. Itching and/or rash.

d. Swelling of lips or tongue or drooling after last dose of medications.

e. Fevers, chills or near fainting

6 The patient has violated the signed Control Order

7 If the authorized licensed nurse or paramedic has questions or needs clarification on orders.

8 Anytime there is a need for medical consultation.

In an emergency situation, the authorized licensed nurse or paramedic shall call 911, provide Basic Life Support if necessary, and emergency services as authorized in the regional emergency SDO. Once first responders arrive and the patient is receiving emergency medical care, notify the treating physician and supervisor by phone as soon as possible.

J. Limitations on Setting

Authorized licensed nurses and paramedics may provide services under these standing delegation orders in the clinic setting, in the patient's home, or other field setting when the treating physician can be contacted by phone.

K. Date and Signature of the Treating Physician

This SDO shall become effective on the date that it is signed by the treating physician, below, and will remain in effect until it is either revised, rescinded, there is a change in the treating physician, or at the end of business on the last day of the current DSHS fiscal year (August 31, 2018), whichever is earlier.

Authorizing Physician's Signature: _____

Authorizing Physician's Title: _____

Printed Name: _____

Effective Date: _____

Emergency Contact Information: _____

Attachment 1

Attestation of Authorized Licensed Nurse or Paramedic

I, _____ have read and understand
printed name of authorized licensed nurse or paramedic

the *Texas Department of State Health Services Standing Delegation Orders for Tuberculosis Clinical Services Provided by Authorized Licensed Nurses and Paramedics, Fiscal Year 2017-18 ("SDO")* that was signed by

_____on_____ printed
name of treating physician date of treating physician's signature

- I agree that I meet all qualifications for authorized licensed nurses or for authorized licensed paramedics as designated in the SDO.
- I agree to follow all instructions faithfully as written in the SDO.

_____

Signature of Authorized Licensed Nurse or Paramedic Date

ATTACHMENT 2
Evaluation of a patient for TB infection (LTBI)

1. If the patient has been reported by an outside medical entity (i.e. hospital, local physician office, etc.), determine if any of the following documentation is available:
    a. Documentation of positive tuberculin skin test (TST) or positive interferon gamma release assay (IGRA).
    b. Documentation of chest X-ray (CXR) that shows no evidence of TB disease.
2. Ask about current signs and symptoms of TB; if patient has one or more:
    a. Contact treating physician.
    b. Begin procedure to evaluate for possible TB disease.
3. If patient <u>does have documentation of a positive TB screening test:</u>
    a. If the patient has not had a CXR in the past month, refer for one.
    b. Determine reason for testing and referral.
    c. Obtain medical risk factors for TB progression.
    d. Determine occupation and public health risk should TB disease develop.
    e. Follow regional TB program guidelines on patients to accept for LTBI treatment.
4. If the patient <u>does not have a documented positive TST or IGRA</u>:
    a. Determine risk factors for exposure to TB and TB progression if infected.
    b. Determine reason for referral.
    c. Follow regional TB program guidelines on patients to accept for LTBI treatment.
5. If the patient is under 5 years of age or immunocompromised:
    a. Perform appropriate TB screening test
    b. Refer for PA and lateral CXR as soon as possible regardless of the result of the TB screening test.
    c. Perform physical examination.
6. Provide the patient's chart to the treating physician to determine treatment plan.

Attachment 3
Evaluation of a patient identified as a contact to a person with TB

1. If the patient has been named as a contact by an individual with TB disease, ensure that the privacy of the index case is maintained throughout the course of the patient's evaluation and management.
2. If patient does have documentation of a positive TB screening test:
    a. History of a positive TST: discuss with the treating physician whether to draw an IGRA.
    b. History of a positive IGRA: refer for CXR.
3. If the patient does not have a documented positive TST or IGRA, place a TST or draw blood for IGRA as appropriate per SDOs.
    a. If patient's TST or IGRA is positive, refer for CXR.
    b. If a QFT is reported as *indeterminate* or a T-Spot is reported as *borderline*, repeat the test.
4. If the patient is under 5 years of age or immunocompromised:
    a. Perform appropriate TB screening test.
    b. Refer for PA and lateral CXR as soon as possible regardless of the result of the TB screening test.
    c. Perform physical examination.
5. If the patient's TB screening test is positive, refer for CXR (see CXR procedure).
6. If the contact has a negative TB screening test and no signs or symptoms of TB, establish a break-in-contact with the index case (the person with infectious TB disease).
    a. Break-in-contact is defined as the date after which the patient is no longer exposed to a person with infectious TB.
    b. If the patient DOES NOT have ongoing exposure, the break-in-contact is the last day spent with the index case without any respiratory protection.
    c. If the contact DOES have ongoing exposure, the break-in-contact is the date when the index case meets the following:
        i. For patients with AFB positive sputum smears:
            1. Three (3) consecutive negative AFB sputum smears collected in 8-24 hour intervals.
            2. Symptomatic improvement.
            3. **Completion of the dose equivalent of 2 weeks of** appropriate multi-drug therapy for TB disease.
            4. Adherent to DOT therapy.
        ii. For patients with negative AFB sputum smears from the beginning:
            1. Three (3) consecutive negative AFB sputum smears collected in 8-24 hour intervals.
            2. Symptomatic improvement.

3. Completion of **at least 5 days** of appropriate multi-drug therapy for TB.
4. Adherent to DOT therapy.

7. If the contact tested negative for TB infection at the initial evaluation, re-screen after 8-10 weeks have passed:
    a. Re-interview for signs and symptoms of TB.
    b. Perform the appropriate TB screening test.
    c. If TB screening test is positive, refer for CXR.
8. If the patient is diagnosed with LTBI, screen for HIV per SDOs.
9. If 8-10 weeks have passed from the break-in-contact when the contact is first evaluated, a second screening appointment is not required.
10. Report findings to treating physician to determine treatment plan.
11. If the patient is to be treated, refer to attachment LTBI Treatment and Management (*Attachment 6*)

Attachment 4
Evaluation of a patient referred through the electronic disease notification system (EDN)

1. Obtain and review all records from the EDN database.
2. Class B1 (TB, Pulmonary, No Treatment) means the person had a CXR suggestive of TB but 3 sputum specimens were a) negative for AFB on smear and negative for TB on culture *OR* b) either negative or positive for AFB on smear but positive for a non-tuberculous mycobacterium on culture.
    a. Obtain medical history including history of TB disease
    b. Ask about current signs and symptoms of TB; if patient has one or more:
        i. Notify treating physician.
        ii. Collect three sputum specimens according to procedure.
        iii. Begin procedure to evaluate for possible TB disease.
    c. Refer for a CXR
    d. Refer for CXR and send along with pre-immigration CXR to radiology for comparison.
    e. If patient has documentation of a positive TST, is ≥ 5 years of age, and comes from a country where BCG vaccinations are given, draw blood for a QFT.
    f. If the patient does not have a documented positive TST or QFT, place TST or draw IGRA as appropriate for age (see TST or venipuncture procedure).
    g. Provide chart to treating physician for review.
3. Class B1 (TB, Pulmonary, documented history of treatment)
    a. Ask about current signs and symptoms of TB; if patient has one or more:
        i. Notify treating physician.
        ii. Collect three sputum specimens according to procedure.
        iii. Begin procedure to evaluate for possible TB disease.
    b. Refer for CXR and send along with pre-immigration CXR to radiology for comparison.
    c. Provide chart to treating physician for review.
4. Class B2 (LTBI evaluation)
    a. Follow procedure for the Evaluation of a patient for possible TB Infection.
    b. If patient is 5 years of age or older and comes from a country with BCG vaccination, draw blood for a QFT.
    c. Refer for CXR and send along with pre-immigration CXR to radiology for comparison.
    d. Provide chart to treating physician for review.

ATTACHMENT 5
Window Prophylaxis

Window Prophylaxis must be provided for anyone exposed to TB who is at high risk for serious complications if infected.

Prophylactic medications **must be directly observed (DOPT).**

1. High risk groups are:
    a. Children under 5 years of age
    b. HIV+ patients
    c. Immunosuppressed patients which include those taking anti-rejection therapy for organ transplant(s) or TNF-α blockers for autoimmune diseases.
2. Counsel patient or patient's parent(s) or caregiver(s) about TB exposure, the risks of serious complications if the patient is infected, and the importance of preventive treatment
3. For children, ask parent(s) or caregiver(s) about signs and symptoms of TB, any changes in behavior, poor feeding, decreased energy, lethargy.
4. For adults, ask about signs and symptoms of TB
5. Obtain a medical history and a list of all medications both prescribed and over the counter including birth control for women.
6. Palpate for lymph nodes.
    a. It is especially important in children to carefully palpate for enlarged lymph nodes in all the locations in the attachment and document the findings (see *Attachment 11)*
    b. For adults, at a minimum palpate axillary and cervical nodes.
7. Place a TST for children *(*procedures in *Attachments 9 and 10)*
8. Draw blood for IGRA adults (venipuncture procedure *Attachment 17)*
9. Send all high risk patients for a CXR as soon as possible, preferably the same day
    a. If CXR is abnormal, provide all records to the treating physician for further orders
    b. If CXR is normal, consult treating physician for window prophylaxis medication orders and begin DOPT as soon as possible.
10. Medication administration
    a. Counsel patient and/or the patient's parent(s) or caregiver(s) about what LTBI is, the purpose of treatment, the medication(s) to be given, and possible toxicities.
    b. Provide DOPT until 8-10 weeks have passed since the patient's last exposure to the source case.
    c. If the patient has suspected or actual continued contact with the source case, provide DOPT until 8-10 weeks have passed since the source case's sputum smears convert to negative.

d. If a child is under 6 months of age, provide DOPT until the child turns 6 months of age and the TST is reliable. (see Attachment 13 for tips on how to give meds to children)
e. Document each DOPT dose, initial, and have patient or patient's parent or guardian initial

11. Repeat TB screening test once the appropriate time frame has passed.
    a. If negative, window prophylaxis may be stopped.
    b. For certain high risk groups (HIV, immunosuppressed), a full course of LTBI treatment should be considered regardless of a negative screening test. Consult the treating physician for orders.

ATTACHMENT 6
LTBI Treatment and Management

1. Counsel the patient or the patient's parent(s) or caregiver(s) about what LTBI is and the risks and benefits of treatment.
2. Obtain consent and provide privacy notice as described earlier in the SDO.
3. Obtain a medical history.
4. Obtain a list of all prescribed or over-the-counter medications, supplements, or herbal remedies (including herbal teas).
5. Ask women about birth control.
    a. Counsel women of child-bearing age of the need to use a barrier method of birth control if Rifampin or Isoniazid/Rifapentine (3HP) are given.
    b. Provide condoms, explain proper use, and inform about availability of female condoms.
6. Draw blood for HIV testing for all patients 13 years of age and older.
7. Discuss medication(s) prescribed by the treating physician and possible adverse events *(*Attachment 12: LTBI Treatment Regimens*)*
8. Draw blood for a baseline CMP and CBC for all patients 13 years of age and older.
9. Instruct patients at the start of treatment and at each monthly visit (with INH or RIF regimens) or weekly visit (with 3HP regimen), to stop taking treatment and to seek medical attention *immediately* if signs or symptoms of hepatotoxicity develop. **Do not wait until the next visit to stop treatment.**
10. Administer LTBI treatment by Directly observed preventive therapy (DOPT) for:
    1) Children under 5 years of age
    2) INH regimens given 2x/week
    3) 3HP regimen
11. Perform a toxicity evaluation monthly
    a. Draw blood for monthly CMP and CBC
        1) For all patients on 3HP, with liver disease, on dialysis, on immunosuppressive medications, positive for HIV, or over 74 years of age OR
        2) As ordered by the treating physician.
    b. Screen for signs and symptoms of medication toxicity: if any are present, **HOLD MEDS** and notify treating physician.
    c. Screen for signs and symptoms of TB: if any are present, refer for a CXR and collect three sputum specimens according to procedure
12. If any of the patient's LFTs (AST, ALT, alkaline phosphatase, and/or total bilirubin) exceeds 3 times the upper limit of normal **AND** the patient has signs and/or symptoms.
    a. Hold medications.
    b. Draw CMP weekly.

c. Consult authorizing physician for orders.

13. When there is a delay in starting treatment, refer the patient for a repeat CXR if:
    a. One month has passed and the patient is at high risk for progression to TB disease (HIV+, ≤ 5 years of age, immunosuppressed)
    b. Three months have passed for all other patients.
14. Calculate doses to determine treatment completion
    a. For the 9 month daily (7days/week) INH regimen, 270 doses must be completed in 12 months
    b. For the 9 months of twice-weekly INH regimen (by DOT ONLY), 76 doses must be completed within 12 months
    c. For the 4 month daily (7days/week) RIF regimen, 120 doses must be completed in 6 months
    d. For the 3HP (12 weeks, once weekly INH & RPT), 12 doses must be completed in 16 weeks. Doses must be separated by ≥72 hours

Attachment 7
Evaluation of a patient with possible TB disease

1. If the patient has been reported by an outside medical facility (i.e. hospital, local physician office, etc.), collect the following information (as available):
    a. Demographics
    b. Laboratory results
    c. Radiographic findings
    d. History and physical report
    e. Any consultation reports from the hospital staff
    f. Current medication list
    g. IGRA or TST results
    h. Bacteriological findings (microbiology results)
    i. Discharge summary
2. Implement location-appropriate isolation (home-based or, if in a congregate setting, facilitate transfer to a negative pressure, isolation (AII) room to prevent the spread of airborne infection).
3. Explain the requirements of isolation and the criteria for isolation to be lifted.
4. Perform a physical examination
5. If the patient does not have documented TST or IGRA, place a TST or draw a QFT (see Venipuncture procedure)
6. If the patient has not received a CXR within the past 2 weeks, refer for a CXR and send it with any previous CXRs to radiology for comparison.
7. Collect at least 3 sputum specimens at 8-24 hour intervals (see sputum collection procedure) and send first specimen for NAAT as well as smear and culture.
    a. If smear and/or NAAT are positive notify treating physician.
    b. If TB is diagnosed, follow procedure for confirmed TB.
8. If there is no documentation of a CBC and/or CMP within the past 14 days, draw blood for them (see venipuncture procedure)
9. Screen for risk factors for Hepatitis B and C (see SDO for criteria) and draw blood for testing if applicable.
10. If the patient is being treated for suspicion of TB disease:
    a. Confirm the dosages of the TB medications based upon the patient's weight (see medication procedures).
    b. Perform baseline toxicity screening to include:
        i. Evaluation of signs and symptoms of hepatotoxicity.
        ii. Measurement of visual acuity and assessment of color vision (using Ishihara plates) if the patient is prescribed Ethambutol.
        iii. If there are any concerns about liver disease, contact treating physician before giving medications.
    c. Administer medications by directly observed therapy.
        i. Have emergency kit available.

ii. Have patient remain in the office or stay with the patient in the field for at least 30 minutes following the first two doses.

d. Perform monthly toxicity screenings.
   i. Evaluation of signs and symptoms of hepatotoxicity and other medication toxicities. If patient reports one or more,
      1. Don't administer medications.
      2. Draw CMP and/or CMP.
      3. Notify treating physician.
   ii. Measure visual acuity and assess color vision (using Ishihara plates) if patient is prescribed Ethambutol.
   iii. Ask about signs and symptoms of TB and whether they're improving or not.
   iv. Measure blood pressure, heart rate, temperature, and weight.

11. After the initiation phase (first 2 months of appropriate treatment), refer patient for CXR.
    a. Send 2 month CXR with baseline CXR to radiology for assessment of treatment response.
    b. Follow-up with treating physician about treatment plan.
12. Compile a list of individuals who may have come into close contact with the patient and test accordingly.
    a. Convene a meeting with contact investigator(s) to determine scope of contact investigation based upon patient's medical evaluation.
    b. Re-interviews the patient as necessary.
13. At least monthly, review clinical, laboratory, and radiological findings with the treating physician to determine treatment plan.

ATTACHMENT 8
Evaluation of a patient with confirmed TB disease

1. If the patient has been reported by an outside medical entity (i.e. hospital, local physician office, etc.), collect the following information (as available):
    a. Demographics
    b. Laboratory results
    c. Radiographic findings
    d. History and physical report
    e. Any consultation reports from the hospital staff
    f. Current medication list
    g. IGRA or TST results
    h. Bacteriological findings (microbiology results)
    i. Discharge summary
2. Explain the requirements of isolation and the criteria for isolation to be lifted.
3. Perform a physical examination.
4. If TB disease is confirmed, a TB screening test is unnecessary.
5. If the patient has not received a CXR within the past 2 weeks, refer for a CXR and send it with any previous CXRs to radiology for comparison.
6. Collect at least 3 sputum specimens at 8-24 hour intervals (see sputum collection procedure).
    a. Send first specimen for NAAT as well as smear and culture.
    b. If sputum specimens are positive for AFB on smear, continue collecting three (3) sputum specimens at 8-24 hour intervals every 2 weeks until there are 3 consecutive sputum specimens negative for AFB on smear.
    c. Once three sputum smears are negative for AFB, collect one sputum per month until there are two consecutive negative TB culture one month apart.
7. If the patient does not have record of a CBC and/or CMP within the past 14 days, draw blood for testing (see venipuncture procedure)
8. Screen for risk factors for Hepatitis B and C (see SDO for criteria) and draw blood for testing if applicable.
9. Confirm the medication dosages based upon the patient's weight (see medication procedures).
10. Perform baseline medication toxicity screening to include:
    a. Evaluation of signs and symptoms of hepatotoxicity.
    b. Measure visual acuity and assess color vision (using Ishihara plates) if the patient is prescribed Ethambutol.
    c. If there are any concerns about liver disease or other patient conditions, contact treating physician before giving medications.
11. Administer medications by directly observed therapy.
    a. Have emergency kit available.
    b. Have patient remain in the office or stay with the patient in the field

for at least 30 minutes following the first two doses.

12. Perform monthly evaluation and toxicity screenings.
    a. Evaluation of signs and symptoms of hepatotoxicity and other medication toxicities. If patient reports one or more,
        i. Do not administer medications.
        ii. Draw CMP and/or CBC.
        iii. Notify treating physician.
    b. Measure visual acuity and assess color vision (using Ishihara plates) if patient is prescribed Ethambutol.
    c. Ask about signs and symptoms of TB and whether they're improving or not.
    d. Measure blood pressure, heart rate, temperature and weight.
13. Begin to compile a list of individuals who may have come into close contact with the patient and test accordingly.
    a. Convene meeting with contact investigator(s) to determine scope of contact investigation based upon patient's medical evaluation.
    b. Multiple interviews with the patient may be necessary.
14. After the initiation phase (first two months of appropriate treatment) has been completed, refer the patient for a CXR and follow-up with treating physician about treatment plan.
15. At least monthly, review clinical, laboratory, and radiological findings with the treating physician to determine treatment plan.

Attachment 9
TST Placement Procedure

When the tuberculin skin test is to be administered in the field, transport and store the PPD in an insulated cooler to protect from heat and light.

A. Before administering,
   1 Confirm that:
      - The PPD has not expired and the vial has not been opened for more than 30 days.
      - The concentration of PPD is 5 tuberculin units (TU) of PPD per test dose of 0.1 mL.
   2 Don exam gloves
   3 When opening a new vial, mark the vial with the date opened.
   4 Fill syringe as soon as PPD is removed from refrigeration to protect from heat.
   5 Clean vial stopper with antiseptic swab.
   6 Draw up slightly more than 0.1 mL of PPD into tuberculin syringe.
   7 Remove excess volume or air bubbles to exactly 0.1 mL of PPD while needle remains in vial to avoid wasting of antigen.
   8 Remove needle from vial.
   9 Return antigen vial to refrigeration immediately after filling.
   10 Use promptly to avoid adsorption onto the syringe.

B. Patient preparation
   1 Rest the patient's arm on a firm, well-lit surface.
   2 Prepare injection site using aseptic technique.
   3 Slightly stretch the skin of the inner aspect of the forearm to facilitate the introduction of the needle. Stretch skin by placing your non-dominant hand on the patient's forearm below the needle insertion point and then applying traction in the opposite direction of the needle insertion. Be careful not to place your non-dominant hand opposite the administration needle if the patient is likely to move during the procedure.

C. Intradermal injection of PPD
   1 Hold the tuberculin syringe close to the skin, bevel up, so that the hub of the needle touches the skin as the needle is introduced.
   2 Insert the needle in the first layer of skin with the tip visible beneath the skin.
   3 Advance the needle through the epidermis (superficial layer of the skin) 3mm so that the entire bevel is covered just under the skin.

4 When the needle is inserted at the correct angle you can see the bevel of the needle just below the skin surface which is important because if it is too deep or too shallow the test is inadequate.
5 Next, release the stretched skin and hold the syringe in place on the forearm.
6 Inject the PPD into the superficial layer of the skin to form a wheal 6 mm to 10 mm in diameter.
7 Remove needle without pressing the skin at the test site and activate the safety feature of the syringe according to manufacturer's recommendations.

D. After administration

1 Place the used needle and syringe in a puncture resistant container without recapping the needle.
2 Immediately measure the wheal to insure that it is 6 mm to 10 mm in diameter.
   - If a wheal does not appear or the wheal is smaller than 6 mm, reapply test at another site at least 5 centimeters (2 inches) from the original site.
   - Document this procedure and the size of the original wheal in the medical record
3 If blood or fluid is present, blot site lightly with gauze or cotton ball and discard used gauze or cotton according to local standard precautions. Do not apply pressure or cover the site with a bandage or other material.
4 Provide instructions to the patient regarding care of the injection site:
   - The wheal (bump) is normal and will remain about 10 minutes.
   - Avoid touching the wheal or scratching close to the injection site.
   - Avoid pressure or bandage on the injection site.
   - May wash with soap and water (without pressure) after 1 hour.
   - No lotions or liquids on site, except for light washing as above.
5 Document the date and time of TST placement, PPD manufacturer, lot number and expiration date, your name, and location of injection site on the appropriate form in the patient's medical record.

Attachment 10
TST Reading Procedure and Interpretation

1. Don exam gloves.

2. Verify the TST was placed at least 48 hours and no longer than 72 hours previously.

3. Place the patient's arm in good light.

4. Flex the patient's forearm slightly at the elbow.

5. Inspect for the presence of induration (hardening or thickening of the tissues) from a side view against the light. Then inspect by direct light to determine if the reaction does not look normal or looks severe (blisters, ulcers or necrosis). Notify TB nurse consultant.

6. Bend patient's arm at elbow to a 90 degree angle and palpate; lightly rub your gloved finger across the injection site from the area of normal skin about two inches from injection site to the area of induration. Do this from four directions. Use zigzag featherlike touch.

7. Repeat palpation with arm bent at elbow at a 45 degree angle to determine presence or absence of induration.

8. Outline the diameter of induration, if present, with a pen by placing marks on both sides of the induration.

9. Erythema (redness) without induration is not significant to the tuberculin skin test result.

10. When the induration is not symmetrical, the transverse (at right angles to the long axis of the body) diameter will usually be smaller.

11. Inspect placement of marks relative to the induration. Repeat finger movements and place additional marks if needed.

12. Note the dots that are transverse (perpendicular) to the long axis of the forearm. To insure consistency, measure the maximum transverse diameter of induration (not erythema) in millimeters, with a flexible ruler.

13. Place the "0" ruler line inside the edge of the medial and read the ruler line inside lateral dot edge. Use the lower measurement if between two gradations on millimeter scale.

14. Record the tuberculin skin test result as a single measurement in millimeters. If there is no induration, record this as 0 millimeters.

An induration of **5 mm or more** is considered to be positive for:

- HIV-infected persons
- Recent contacts to a known TB case
- Individuals with fibrotic changes on chest radiograph consistent with old TB
- Persons with organ transplants and other immunosuppressed persons
    - On chemotherapy for cancer
    - Taking greater than or equal to 15 mg/day prednisone for longer than 1 month
    - Taking TNF alpha blockers (Infliximab [Remicade], Adalimiumab [Humira], Certolizumab [Cimzia], Etanercept [Enbrel], Golimumab [Simponi]).

2. An induration of **10 mm or more** is considered to be positive for:
    - Recent arrivals (less than 5 years) from high-prevalence countries
    - Injection drug users
    - Residents and employees of high-risk congregate settings: correctional facilities, nursing homes and other healthcare or long-term care facilities, residential facilities for AIDS patients, and homeless shelters
    - Mycobacteriology laboratory personnel
    - Persons with high-risk clinical conditions: silicosis, diabetes mellitus, chronic renal failure, some hematologic disorders (e.g., leukemias and lymphomas), other specific malignancies (e.g., carcinoma of the head or neck and lung), weight loss of > 10% of ideal body weight, gastrectomy, jejunoileal bypass
    - Children younger than 4 years of age
    - Infants, children, and adolescents exposed to adults in high-risk categories

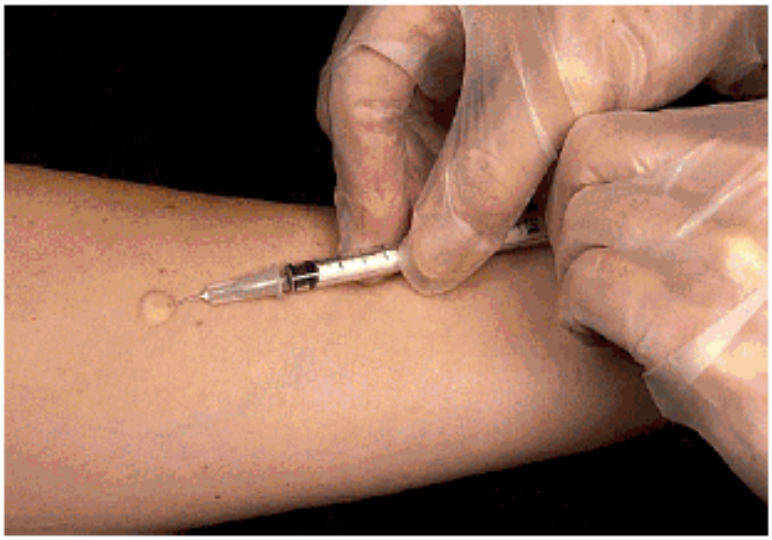
3. An induration of **15 mm or more** is considered to be positive in individuals with no known risk factors for tuberculosis.

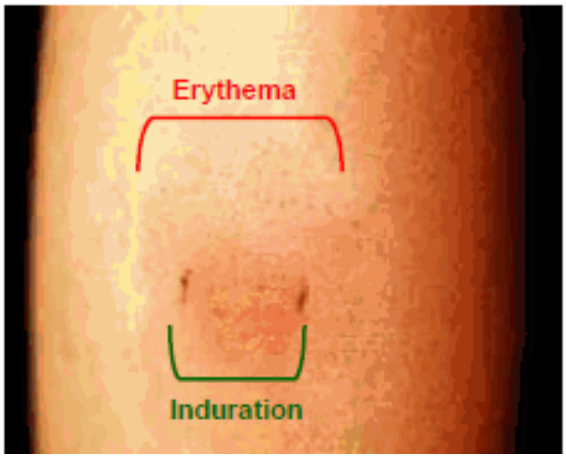
INTERPRETATION

Reading a Tuberculin Skin Test:

Induration not erythema is measured! Measure the induration laterally across the forearm. Measure with a millimeter ruler. The TST is positive if the induration measures:

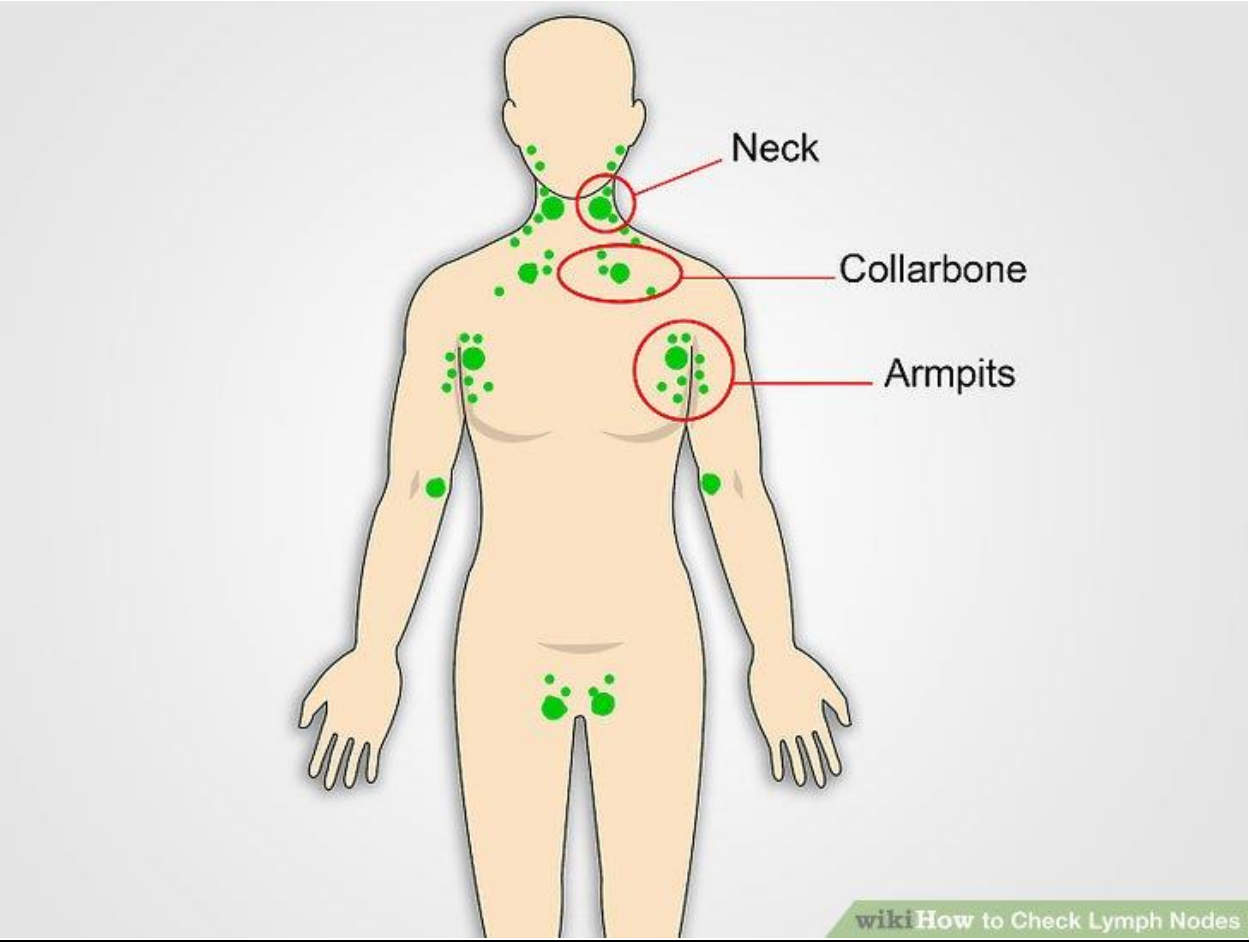
- ≥ 5mm in HIV co-infection, immunocompromised, recent TB contact, suspected disease
- ≥ 10mm in foreign born from a high risk country, drug use, living in HR (High Risk) congregate setting, children ≤ 4, specific HR groups
- ≥ 15mm with no risk factor





Attachment 11

Diagram of Anatomical Location of Lymph Nodes



ATTACHMENT 12
Latent TB Treatment Regimens and 3HP Dosages

Drug(s)	Duration	Dose	Frequency	Total Doses
Isoniazid (INH)	9 months	Adult: 5 mg/kg Children: 10-20 mg/kg** Maximum dose: 300 mg	Daily	270
		Adult:15 mg/kg Children: 20-40 mg/kg** Maximum dose: 900 mg	Twice weekly†	76
	6 months	Adult: 5 mg/kg Children: Not recommended Maximum dose: 300 mg	Daily	180
		Adult: 15 mg/kg Children: Not recommended Maximum dose: 900 mg	Twice weekly†	52
Isoniazid (INH) and Rifapentine (RPT)	3 months	Adults and Children 12 years of age and over: **INH*:** 15 mg/kg rounded up to the nearest 50 or 100 mg; 900 mg maximum **RPT*:** 10.0–14.0 kg 300 mg 14.1–25.0 kg 450 mg 25.1–32.0 kg 600 mg 32.1–49.9 kg 750 mg ≥*50.0 kg 900 mg maximum*	Once weekly†	12
Rifampin (RIF)	4 months	Adult: 10 mg/kg*** Maximum dose: 600 mg	Daily	120

https://www.cdc.gov/tb/publications/ltbi/treatment.htm#treatmentRegimen

The 3HP regimen is not recommended for children younger than 2 years of age

Attachment 13
"Tuberculosis Medication Delivery Tips" from Anne Loeffler, MD

Liquid:

- INH suspension is available commercially in sorbitol. The large osmotic load is poorly tolerated by most children as it can cause diarrhea, but it may be better tolerated by babies.
- Other TB medications are not commercially available as liquids. Medications may be suspended by local pharmacies but the stability and homogeneity are not guaranteed.

Pills and capsules taken intact or in halves: This is the easiest way! Tip the head back to swallow pills and tip the head forward to swallow capsules. If the child can swallow capsules, but not tablets, crush the pulls and place the powder in commercially available empty capsules

Pills fragmented or crushed; capsules can be opened. The crushed pills have a strong flavor; small fragments of the pill taste better. Crush or fragment pills right before administering (within 30 minutes). Two strategies:

- Put a thin layer of soft food onto a spoon. Place the pill fragments or powder on top of the food layer and top with more yummy food. Give the child the dose of medication in this "sandwich." Teach them to swallow it without chewing by practicing without the medication in place first. Some suggested foods:
    - Chocolate frostings, sauce, pudding, fudge sauce, ice cream, etc.
    - Jelly or marmalade (the texture hides the powder granularity)
    - Apple sauce or berry-sauce (better to hide the red rifampin)
    - Nutella or peanut butter
    - Cream cheese or chili con carne
    - Whatever the family can make work
- Suspend in a SMALL AMOUNT of liquid. Water is best. (INH is not stable in sugary liquids) Dispense with:
    - Syringe (difficult for the pulverized INH but other drugs are finer)
    - Medicine dropper with larger tip; available at many pharmacies
    - Baby bottle (may need to make hole larger)
    - Special Rx MediBottle with internal sleeve for syringe; available at many pharmacies. Pulverized INH is very difficult to get through this syringe. I suggest giving the other meds with this bottle and then giving INH separately or by the liquid product if it is tolerated by the baby.
    - Medicine delivering pacifier; available at many pharmacies (holes will need to be enlarged)

ATTACHMENT 14
Procedure for Collecting Sputum Specimens

1. If the patient is still infectious:
    a. Wear N-95 mask and instruct patient to wear surgical mask when meeting with patient in a confined space.
    b. If clinic does not have negative pressure room(s) or if there are others in the patient's home, collect sputum outside.
2. Review the purpose for sputum collection and how to produce a quality specimen from deep in the lungs instead of saliva.
3. Label the innermost tube with the patient's name and date of birth before obtaining a sputum specimen or giving container(s) to the patient for collection at a later time.
4. Provide the following instructions to the patient:
    a. Rinse mouth well with water to avoid contamination with food particles and mouth bacteria. Ideally, sputum specimen collection should occur before eating.
    b. Inhale deeply two to three times, breathe out hard each time.
    c. Cough deeply from the chest. A deeply coughed specimen is required so that it is not saliva or nasal secretions.
    d. Place the open container close to the mouth to collect the TB sputum specimen. The ideal specimen size is 5 to 10 mL, but 3 to 15ml is acceptable.
    e. Avoid contaminating the inside of the container and lid by contact with the mouth or hand.
2. Supervise at least one (ideally the first) sputum collection to document that the patient demonstrates the correct technique.
3. If sputum collection is observed, collect container from the patient, close the lid tightly, and place into the TB sputum specimen bag.
4. If collection of the sputum specimens will occur at a later time, instruct the patient how to handle the tubes and containers correctly. Instruct the patient to store the sputum specimen(s) in a refrigerator until they are picked up by TB staff or how to package the specimens correctly to mail directly to the laboratory.
5. If the patient is unable to produce an early morning sputum, suggest that he/she take a hot, steamy bath or shower for 15 minutes, if possible, before attempting to collect sputum.
6. If the patient is unable to produce an acceptable sputum specimen, follow the procedure for TB sputum induction in Attachment 15: Sputum Induction Procedure.

ATTACHMENT 15
Sputum Induction Procedure

1. Explain the purpose of the nebulizer, why it is being used, and how it works.

2. Assemble nebulizer according to directions.

    a. Attach one end of air tubing to compressor unit and other end to the nebulizer medication cup outlet.

    b. With machine turned off, prepare the nebulizer equipment as per package instructions. Add approximately 3 mL of sterile 0.9% sodium chloride (NaCl) solution to the nebulizer medication cup.

3. Turn compressor on and assist, if necessary, with placement of the mouthpiece correctly into the patient's mouth.

4. Encourage patient to breathe in slowly and deeply.

5. Instruct patient to cough if no spontaneous coughing occurs.

6. Continue procedure until cough is stimulated, adding more sterile 0.9% NaCl solution as needed.

7. When a cough is stimulated, encourage several repetitions in order to obtain an adequate specimen (at least 5 mL).

8. Upon completion, turn off the nebulizer and pack it up.

9. Label and package the TB sputum specimen correctly and legibly. Mark lab requisition as "induced specimen".

10. Disassemble mouthpiece and disinfect nebulizer according to manufacturer instructions.

ATTACHMENT 16

Procedure for Packaging and Shipping Sputum Specimens

1. Once a sputum specimen is obtained, label the innermost tube with the patient's name and date of birth.
2. Correctly package the specimen(s) according to shipping requirements and procedures.
    a. Sputum specimens must be packed in triple containment with sufficient absorbent material enclosed to absorb the entire volume of liquid.
    b. The container used *must* meet current Texas Department of Transportation and United States Postal Service regulations.
3. Complete the lab requisition G-MYCO form and designate specimen as sputum or induced sputum if the nebulizer was used.
4. If the sputum specimens cannot be delivered to the laboratory within 1 hour of collection, the specimens must be refrigerated.
5. Ship the refrigerated sputum specimens on cold pack(s) to the DSHS laboratory as soon as possible.

ATTACHMENT 17: Venipuncture Procedure

1. Utilize interpreter services to facilitate patient and staff communication as it relates to limited English proficient (LEP) patients.
2. Adhere to all Universal/Standard Precautions, including bloodborne and respiratory precautions when participating in blood specimen collection procedures.
3. Ensure, to the extent possible, that the person seen for blood specimen collection services is, in fact, who the person claims to be.
4. Ensure that the patient's consent and signature have been obtained by the nurse responsible for the clinical management of the patient, or by other DSHS staff responsible to obtain blood specimens as part of evaluation for communicable disease or infection. If consent and signature have not been obtained, then obtain consent and signature in accordance with agency policy and provide copies of the ***DSHS Privacy Notice*** and applicable signed consent forms.
5. Verify the order.
6. Explain the blood specimen collection process. Discuss with the patient the risks and benefits of blood specimen collection. Provide the opportunity for the patient to ask and receive satisfactory answers to questions. If the patient has questions you cannot answer, contact the healthcare provider responsible for the clinical management of the patient for instructions.
7. Gather the required supplies and prepare to collect the blood specimen sample(s).
8. Wash, rinse, and dry hands thoroughly using soap, hand antiseptic, or surface antiseptic from a dispenser.
9. Wear disposable latex examination gloves, or a suitable equivalent, during every vascular access procedure.
10. Perform venipuncture as follows.
11. Assess patient for an acceptable site to perform venipuncture.
12. Median cubital and cephalic veins are the optimal choices and provide the least risk of nerve damage.
13. If those sites are unacceptable, the cephalic vein on the superior lateral aspect of the wrist (thumb side) or metacarpal (hand) veins may be used. (see Fig. 1 below).
14. At no time should veins on the feet, legs, or palmar aspect of the hands be used.
15. Factors to consider in site selection:
    a. Extensive scarring or healed burn areas should be avoided.
    b. Specimens should not be obtained from the arm on the same side as a mastectomy. Lymphostasis may occur.
    c. Avoid areas of hematoma.
    d. Do not obtain specimens from an arm having a cannula, fistula, or vascular graft.

16. Position patient, extending upper extremity comfortably.
17. Verify blood specimen tubes to be used correspond to tests requested and are not expired.
18. Apply tourniquet 3-4 inches above the selected puncture site. Do not leave tourniquet on more than 2 minutes.
19. Ask the patient to make a fist without pumping his/her hand.
20. Cleanse puncture site with alcohol in circular pattern, beginning at site and working outward. Allow to air dry.
21. Remove needle cap.

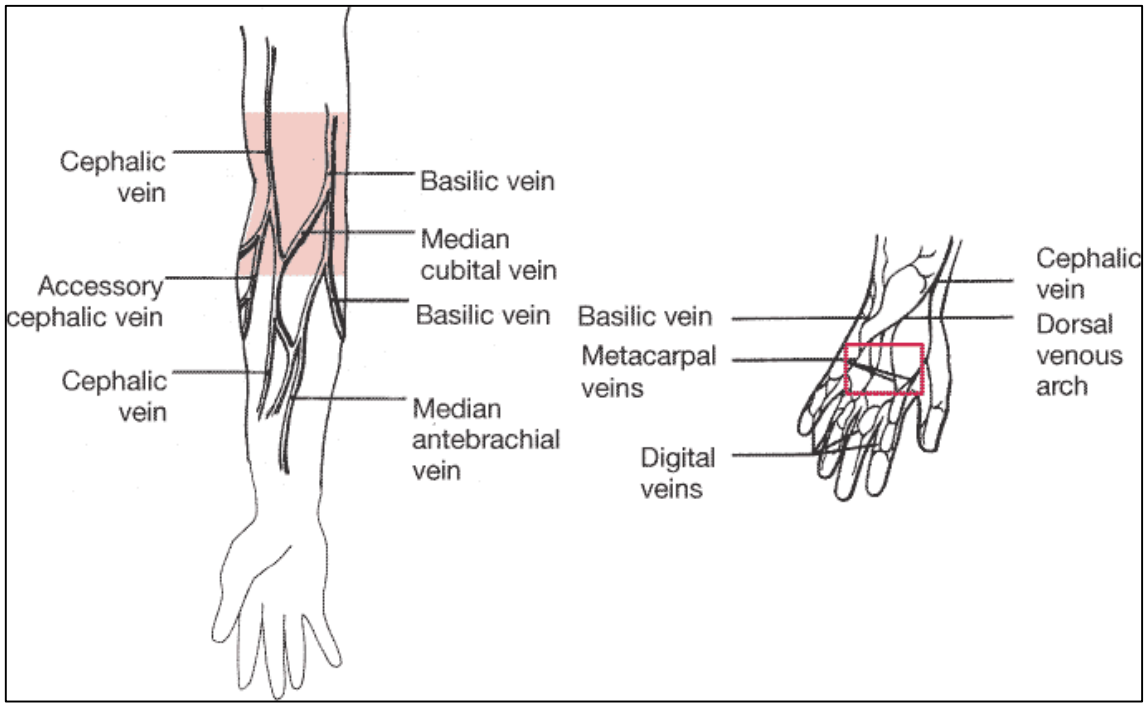


Figure 1

22. Draw skin taut to anchor the vein.
23. Insert the needle (bevel up) at a 15- to 30-degree angle, avoiding trauma and excessive probing.
24. Hold needle completely still while inserting tubes onto vacutainer. Fill blood specimen tubes in correct order, if order specified.
25. Remove the tourniquet as the last blood specimen tube is filling and ask patient to open fist.
26. Remove the last blood specimen tube.
27. Remove the needle from the patient's arm using a swift backward motion. While withdrawing the needle from the patient's skin, engage the safety mechanism.
28. Press down on gauze over the puncture site with adequate pressure or ask patient to apply direct pressure on gauze over the puncture site while

keeping arm straight.

29. Place the needle into the sharps container.
30. Gently invert the tubes 5 to10 times, or per the specific procedure required by the laboratory for the blood test to be performed, and correctly label all tubes while at the patient's side.
31. Assure that puncture site bleeding has stopped. Apply adhesive bandage, if necessary.
32. Remove gloves and discard in an appropriate waste container.
33. Instruct the patient on when and where to follow up for results or additional testing.
34. Instruct the patient on what conditions require a medical re-evaluation.
35. Label and correctly package the specimen, according to laboratory and shipping requirements and regional procedures. Submit specimen to an approved laboratory for processing.
36. Document all specimen collection dates, test types, and circumstances affecting collection, including adverse events, on the applicable form and in the patient's medical record, if applicable.
37. In the event of an adverse event, such as fainting by the patient, provide appropriate supportive measures and notify the healthcare provider responsible for the clinical management of the patient
38. In the case of blood-borne pathogen exposure, wash the site and report to the supervisor immediately.
39. Wash hands and change gloves between every patient.

Attachment 18
Treatment Regimens for Susceptible Tuberculosis

Table 2. Drug Regimens for Microbiologically Confirmed Pulmonary Tuberculosis Caused by Drug-Susceptible Organisms

	Intensive Phase		Continuation Phase				
Regimen	Drug[a]	Interval and Dose[b] (Minimum Duration)	Drugs	Interval and Dose[b,c] (Minimum Duration)	Range of Total Doses	Comments[c,d]	Regimen Effectiveness
1	INH RIF PZA EMB	7 d/wk for 56 doses (8 wk), or 5 d/wk for 40 doses (8 wk)	INH RIF	7 d/wk for 126 doses (18 wk), or 5 d/wk for 90 doses (18 wk)	182–130	This is the preferred regimen for patients with newly diagnosed pulmonary tuberculosis.	Greater
2	INH RIF PZA EMB	7 d/wk for 56 doses (8 wk), or 5 d/wk for 40 doses (8 wk)	INH RIF	3 times weekly for 54 doses (18 wk)	110–94	Preferred alternative regimen in situations in which more frequent DOT during continuation phase is difficult to achieve.	
3	INH RIF PZA EMB	3 times weekly for 24 doses (8 wk)	INH RIF	3 times weekly for 54 doses (18 wk)	78	Use regimen with caution in patients with HIV and/or cavitary disease. Missed doses can lead to treatment failure, relapse, and acquired drug resistance.	
4	INH RIF PZA EMB	7 d/wk for 14 doses then twice weekly for 12 doses[e]	INH RIF	Twice weekly for 36 doses (18 wk)	62	Do not use twice-weekly regimens in HIV-infected patients or patients with smear-positive and/or cavitary disease. If doses are missed, then therapy is equivalent to once weekly, which is inferior.	Lesser

Abbreviations: DOT, directly observed therapy; EMB, ethambutol; HIV, human immunodeficiency virus; INH, isoniazid; PZA, pyrazinamide; RIF, rifampin.

[a] Other combinations may be appropriate in certain circumstances; additional details are provided in the section "Recommended Treatment Regimens."

[b] When DOT is used, drugs may be given 5 days per week and the necessary number of doses adjusted accordingly. Although there are no studies that compare 5 with 7 daily doses, extensive experience indicates this would be an effective practice. DOT should be used when drugs are administered <7 days per week.

[c] Based on expert opinion, patients with cavitation on initial chest radiograph and positive cultures at completion of 2 months of therapy should receive a 7-month (31-week) continuation phase.

[d] Pyridoxine (vitamin B6), 25–50 mg/day, is given with INH to all persons at risk of neuropathy (eg, pregnant women; breastfeeding infants; persons with HIV; patients with diabetes, alcoholism, malnutrition, or chronic renal failure; or patients with advanced age). For patients with peripheral neuropathy, experts recommend increasing pyridoxine dose to 100 mg/day.

[e] See [426]. Alternatively, some US tuberculosis control programs have administered intensive-phase regimens 5 days per week for 15 doses (3 weeks), then twice weekly for 12 doses.

Attachment 19: Doses of First-Line TB Medications

TABLE 2. Doses of First-Line Antituberculosis Drugs for Adults and Children

			Doses		
Drug	**Preparation**	**Adults/children**	**Daily**	**2x/wk**	**3x/wk**
Isoniazid (INH)*	Tablets (100 mg, 300 mg); elixir (50 mg/5 ml)	Adults (max.)	5 mg/kg (300 mg)	15 mg/kg (900 mg)	15 mg/kg (900 mg)
		Children (max.)	10–15 mg/kg (300 mg) See TABLE 6	20–30 mg/kg (900 mg) See TABLE 6	—
Rifampin†	Capsule (150 mg, 300 mg); (powder may be suspended for oral administration –Contact Pharmacy Branch for details)	Adults (max.)	10 mg/kg (600 mg)	10 mg/kg (600 mg)	10 mg/kg (600 mg)
		Children (max.)	10–20 mg/kg (600 mg) See TABLE 6	10–20 mg/kg (600 mg) See TABLE 6	—
Pyrazinamide	Tablet (500 mg, scored)	Adults	See TABLE 3	See TABLE 3	See TABLE 3
		Children (max.)	30-40 mg/kg (2.0 g) See TABLE 6	50 mg/kg (2.0 g) See TABLE 6	—
Ethambutol	Tablet (100 mg, 400 mg)	Adults	See TABLE 4	See TABLE 4	See TABLE 4
		Children (max.)	15–25 mg/kg (1.0 g) See TABLE 6	50 mg/kg (2.5 g) See TABLE 6	—

Table adapted from Treatment of Tuberculosis. MMWR. 2003; 52(RR11). http://www.cdc.gov/mmwr/pdf/rr/rr5211.pdf

Table 10. Suggested Pyrazinamide Doses, Using Whole Tablets, for Adults Weighing 40–90 kg[a]

	Weight, kg[b,c]		
Regimen	40–55	56–75	76–90
Daily (mg/kg)	1000 mg (18.2–25.0)	1500 mg (20.0–26.8)	2000 mg (22.2–26.3)
Thrice weekly (mg/kg)	1500 mg (27.3–37.5)	2500 mg (33.3–44.6)	3000 mg (33.3–39.5)
Twice weekly (mg/kg)	2000 mg (36.4–50.0)	3000 mg (40.0–53.6)	4000 mg (44.4–52.6)

[a] With normal renal function.
[b] Based on estimated lean body weight. Optimal doses for obese patients are not established.
[c] Numbers in parentheses are the calculated mg/kg doses for patients at the highest and lowest body weights in the weight band.

Table 11. Suggested Ethambutol Dosages, Using Whole Tablets, for Adults Weighing 40–90 kg[a]

	Weight, kg[b,c]		
Regimen	40–55	56–75	76–90
Daily (mg/kg)	800 mg (14.5–20.0)	1200 mg (16.0–21.4)	1600 mg (17.8–21.1)
Thrice weekly (mg/kg)	1200 mg (21.8–30.0)	2000 mg (26.7–35.7)	2400 mg (26.7–31.6)
Twice weekly (mg/kg)	2000 mg (36.4–50.0)	2800 mg (37.3–50.0)	4000 mg (44.4–52.6)

[a] With normal renal function.
[b] Based on estimated lean body weight. Optimal doses for obese patients are not established.
[c] Numbers in parentheses are the calculated mg/kg doses for patients at the highest and lowest body weights in the weight band.

Attachment 20

Table 12. Dosing Recommendations for Adult Patients With Reduced Renal Function[a]

Drug	Change in Frequency?	Recommended Dose and Frequency for Patients With Creatinine Clearance <30 mL/min, or Patients Receiving Hemodialysis
Isoniazid	No	300 mg once daily, or 900 mg 3 times/wk
Rifampin	No	600 mg once daily, or 600 mg 3 times/wk
Pyrazinamide	Yes	25–35 mg/kg/dose 3 times/wk (not daily)
Ethambutol	Yes	20–25 mg/kg/dose 3 times/wk (not daily)
Levofloxacin	Yes	750–1000 mg/dose 3 times/wk (not daily)
Moxifloxacin	No	400 mg once daily
Cycloserine	Yes	250 mg once daily, or 500 mg/dose 3 times/wk[b]
Ethionamide	No	250–500 mg/dose daily
Para-amino salicylic acid	No	4 g/dose twice daily
Streptomycin	Yes	15 mg/kg/dose 2-3 times/wk (not daily)
Capreomycin	Yes	15 mg/kg/dose 2-3 times/wk (not daily)
Kanamycin	Yes	15 mg/kg/dose 2-3 times/wk (not daily)
Amikacin	Yes	15 mg/kg/dose 2-3 times/wk (not daily)

- Standard doses are given unless there is intolerance.
- The medications should be given after hemodialysis on the day of hemodialysis.
- Monitoring of serum drug concentrations should be considered to ensure adequate drug absorption, without excessive accumulation, and to assist in avoiding toxicity.
- Data currently are not available for patients receiving peritoneal dialysis. Until data become available, begin with doses recommended for patients receiving hemodialysis and verify adequacy of dosing using serum concentration monitoring.
- In patients with 30–50 mL/min creatinine clearance, standard doses are used by experts, but measurement of serum concentrations 2 and 6 hours after timed administration can be used to assist with optimizing drug dosages.

[a] Including adult patients receiving hemodialysis.

[b] The appropriateness of 250-mg daily doses has not been established. There should be careful monitoring for evidence of neurotoxicity.

Attachment 21

Pediatric Dosing for First-Line TB Medications

DAILY DOSE RANGE*				
Child's Weight (kg)	**Isoniazid (INH)** 10-15 mg/kg/day Dose, mg Max dose: 300mg	**Rifampin (RIF)** 10-20 mg/kg/day Dose, mg Max dose: 600mg	**Pyrazinamide (PZA)** 30-40 mg/kg/day Dose, mg Max dose: 2000mg	**Ethambutol (EMB)** 15-25 mg/kg/day Dose, mg Max dose: 1000mg
3-5	50	50	125	50-100
6-9	100	100	250	150
10-15	150	150	375-500	250
16-20	200	200	500-750	300
21-25	300	300	750	400
26-45	300	450	1000-1500	600-700
46-50	300	600	1500-2000	800
51-66	300	600	2000	1000
67+	300	600	2000	1000
Forms available:	Scored tablets: 100 mg 300 mg Syrup: 10 mg/ml†	Capsules: 150 mg 300 mg Syrup: compounded formulation	Scored tablets: 500 mg	Tablets: 100 mg 400 mg

Attachment 22
Procedure for Self-Administration Packets

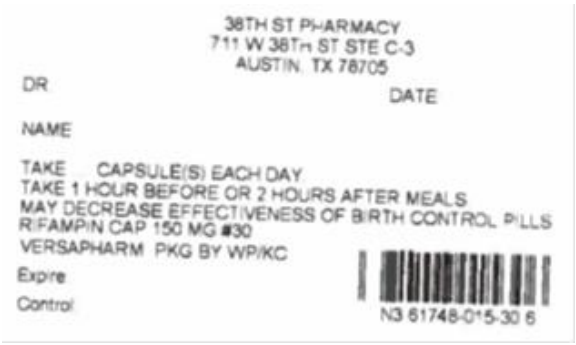
1. Instruct patient to take all medications in the packet at one time.

2. Mark these on the DOT form as self-administered doses. They do not count toward the patient's total dose count.

3. Verify that the medication label is correct and includes the following, either pre-printed by the pharmacy or hand-written:

    a. The patient 's name
    b. Date medication is provided
    c. The physician's name
    d. The name, address, and telephone number of the clinic
    e. The name and strength of the drug - if generic name, the name of the manufacturer or distributor of the drug
    f. Quantity of each drug
    g. Lot number and expiration date

    See sample label:


38TH ST PHARMACY
711 W 38TH ST STE C-3
AUSTIN, TX 78705
DR
DATE
NAME
TAKE CAPSULE(S) EACH DAY
TAKE 1 HOUR BEFORE OR 2 HOURS AFTER MEALS
MAY DECREASE EFFECTIVENESS OF BIRTH CONTROL PILLS
RIFAMPIN CAP 150 MG #30
VERSAPHARM PKG BY WP/KC
Expire
Control
N3 61748-015-30 6